UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,660	11/28/2005	Gunther Harth	51326-00005 NAT	6518

45200 7590 07/02/2009

K&L Gates LLP
1900 MAIN STREET, SUITE 600
IRVINE, CA 92614-7319

EXAMINER	
OLSON, ERIC	
ART UNIT	PAPER NUMBER
1623	
MAIL DATE	DELIVERY MODE
07/02/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,660	HARTH ET AL.	
	Examiner	Art Unit	
	ERIC S. OLSON	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5,7,10-13 and 15-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5, 7, 10-13, and 15-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

This office action is a response to applicant's communication submitted December 12, 2008 wherein claim 5 is amended and new claims 17-22 are introduced. This application is a national stage application of PCT/US03/36705, filed November 17, 2003, which claims benefit of provisional applications 60/426502, filed November 15, 2002, and 60/430407, filed December 2, 2002.

Claims 5, 7, 10-13, and 15-22 are pending in this application.

Claims 5, 7, 10-13, and 15-22 as amended are examined on the merits herein.

The following rejections of record in the previous office action are maintained:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5, 7, 10, 12, 13, 15-20, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Stamler et al. (US patent 6057367, of record in previous action)

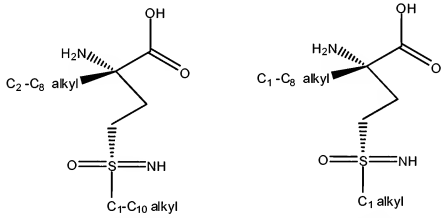
Stamler et al. discloses a method of killing or reducing the growth of pathogenic microbes in mammals such as humans by selective manipulation of nitrosative stress. (column 2 lines 32-40) Pathogenic microbes include mycobacteria such as *Mycobacterium tuberculosis, Mycobacterium leper*, and *Salmonella typhi*. (column 3 lines 7-18) This method includes administering compounds such as alpha-alkyl-S-alkyl

homocysteine sulfoximines, particularly racemic DL,RS mixtures or the single L,S diastereomer. (column 14 line 65 – column 15 line 12) These compounds are described as having an alpha alkyl of 2-8 carbons, which meets the definition of R_1 in the instant claims, and an S-alkyl of 1 to 10 carbon atoms. One skilled in the art would at once envisage these compounds as including the specific S-methyl compound which is a methionine sulfoximine according to the instant claims. Therefore the claimed invention is anticipated by Stamler et al.

Response to Argument: Applicant's arguments, submitted December 12, 2008, with respect to the above grounds of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant argues that the reference does not disclose a method of inhibiting mycobacterial glutamine synthetase, but rather discloses a method of manipulating nitrosative stress to kill or reduce the growth of pathogenic microbes. However, according to MPEP 2111.02, If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). See also Rowe v. Dror, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) In the instant case, the body of the claim defines both the subject population (a mammal having a mycobacterial infection) and the therapeutic agent. (alpha-alkylated methionine sulfoximine) Therefore the preamble is not considered a

limitation and has no significance to claim construction. In other words, as the actual structural limitations, namely the administered compound and the subject population, of the claim and the prior art are the same, the claim and the prior art are seen to have the same scope, indicating that the prior art anticipates the claim.

Applicant further argues that the claims have been amended to require that the compound not inhibit gamma-gluamylcysteine synthetase, which is listed in the prior art reference as an effect of the disclosed prior art compounds. However, reciting particular effects of the claimed compound does not serve to differentiate the claims over the prior art when the prior art anticipates the claims under 35 USC 102. In the instant case, Stamler et al. discloses a chemical formula comprising alpha-alkyl, S-alkyl homocysteine sulfoximines, which encompass the claimed compounds as shown below:



Compoiunds of Stamler et al. Claimed compounds

Figure 1 - comparison of the compounds of Stamler et al. to those of the claimed invention.

The instantly claimed compounds are a subset of the compounds of Stamler et al. wherein the S-alkyl group is a methyl group. Since one skilled in the art would have

at once envisaged C_1-C_{10} alkyl as including methyl as a specific embodiment, Stamler et al. specifically discloses the claimed compounds. These are the same compounds whether they are disclosed in Stamler et al. or in the instant invention. Therefore any further recitation of inherent properties of these compounds fails to differentiate the compounds from the prior art.

For these reasons the rejection is deemed proper and made **FINAL**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stamler et al. (US patent 6057367, cited in PTO-892) in view of the Merck Manual of Diagnosis and Therapy, Seventeenth Edition. (Reference included with PTO-892, herein referred to as Merck)

The disclosure of Stamler et al. is discussed above. Stamler et al. does not disclose a method further comprising administering isoniazid.

Merck discloses that Isonazid is a commonly used drug for the treatment of tuberculosis and is used in combination with other therapeutic agents. (p. 1196, table 157-6, p. 1197 left column second paragraph)

It would have been obvious to one of ordinary skill in the art at the time of the invention to co-administer the therapeutic compounds of Stamler et al. with Isonazid. One of ordinary skill in the art would have been motivated to combine these two compounds because they are both shown in the prior art to be useful for the same purpose, namely treating *Mycobacterium tuberculosis* infection. One of ordinary skill in the art would reasonably have expected success because combining two known compositions that are disclosed in the art to be useful for the same purpose is well within the ordinary and routine level of skill in the art.

Response to Argument: Applicant's arguments, submitted December 12, 2008, with respect to the above grounds of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant's arguments are the same as those made with respect to the rejection over Stamler et al. above and are not found to be persuasive for the same reasons. Therefore the rejection is deemed proper and made **FINAL**.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 5, 7, 10, 12, 13, 15-20, and 22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6057367. (of record in previous action, herein referred to as '367) Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-6 of '367 anticipate the claimed invention. In particular, these claims are directed to a method for treating a microbial infection by administering an inhibitor of glutathione synthesis that is an alpha-alkyl-s-alkyl homocysteine derivative having an alpha alkyl group that is 2-8 carbons and an S-alkyl group that is 1-10 carbons. One skilled in the art would at once envisage these compounds as including the specific S-methyl compound which is a methionine sulfoximine according to the instant claims. Pathogenic microbes are disclosed in the specification to include mycobacteria such as *Mycobacterium tuberculosis, Mycobacterium leper*, and *Salmonella typhi*. (column 3 lines 7-18) Thus claims 1-6 of '367 anticipate the claimed invention.

Response to Argument: Applicant's arguments, submitted December 12, 2008, with respect to the above grounds of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant's arguments are the same as those made with respect to the rejection over Stamler et al. above and are not found to

be persuasive for the same reasons. Therefore the rejection is deemed proper and made **FINAL**.

Conclusion

No claims are allowed in this application. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC S. OLSON whose telephone number is (571)272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/
Examiner, Art Unit 1623
6/30/2009

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623